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10/807,835	03/24/2004	Timothy H. Joyce	02220197P003aUS	4327

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SONNENSCHN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER

CORDERO GARCIA, MARCELA M

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1654

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,835	Applicant(s) JOYCE, TIMOTHY H.	
	Examiner Marcela M. Cordero Garcia	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-22, 49-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, drawn to claims 1-22 and 49-50 in the reply filed on October 29, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In response to the election of species requirement, Applicant elects to prosecute the species comprising: "a cyclic D,L- α -peptide" for the peptide, "a naturally occurring lipid" for the lipid, an "activatable inactivated organic nanotube", "activatable by a change in pH". Claims 1-6, 11-22 and 49-50 are readable thereon. Claims 7-10 are withdrawn as not drawn to the elected species.

Claims 1-6, 11-22 and 49-50 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 11-22 and 49-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a liposome for introducing an organic nanotube in a cell, comprising: (a) a lipopeptide, said lipopeptide including a lipid covalently attached to a peptide; and (b) an inactivated organic nanotube enclosed in the liposome. In regards to the terms "liposome", "lipopeptide" and "organic nanotube", these are very broad generic statements drawn to many

structures of different molecular composition, which are not adequately described and/or represented in the examples. The claims are drawn to "vesicles" or "encapsulation vesicles" which refer to an entity that is generally characterized by the presence of one or more walls or membranes that form one or more internal voids. Vesicles may be formulated, for example, from a stabilizing material such as a lipid, including the various lipids described herein, a proteinaceous material, including the various proteins described herein, and a polymeric material, including the various polymeric materials described herein. As discussed herein, vesicles may also be formulated from carbohydrates, surfactants, and other stabilizing materials, as desired. The lipids, proteins, polymers and/or other vesicle forming stabilizing materials, may be natural, synthetic or semi-synthetic. Preferred vesicles are those which comprise walls or membranes formulated from lipids. The walls or membranes may be concentric or otherwise. The stabilizing compounds may be in the form of one or more monolayers or bilayers. In the case of more than one monolayer or bilayer, the monolayers or bilayers may be concentric. Stabilizing compounds may be used to form a unilamellar vesicle (comprised of one monolayer or bilayer), an oligolamellar vesicle (comprised of more than about three monolayers or bilayers). The walls or membranes of vesicles may be substantially solid (uniform), or referred to as, for example, liposomes, lipospheres, nanoliposomes, particles, micelles, bubbles, microbubbles, microspheres, nanospheres, nanostructures, microballoons, microcapsules, aerogels, clathrate bound vesicles, hexagonal/cubic/hexagonal II phase structures, and the like. The internal void of the vesicle may be filled with a wide variety of materials including, for example, water, oil, gases, gaseous precursors, liquids, fluorinated compounds or liquids, liquid-perfluorocarbons, liquid perfluoroethers, therapeutics, bioactive agents, if desired, and/or other materials. The vesicles may also comprise a targeting ligand if desired

([0056] of the publication of the present application). With regards to the lipopeptides, the disclosure ([0021]) teaches that the lipopeptides comprise a lipid covalently attached to a peptide by means of an amide bond, however, does not provide guidance with regards to the peptide sequences and is very broad with regards to the covalently attached peptides: [0036] "Lipid" refers to a naturally occurring, synthetic or semi-synthetic (i.e. modified natural) compound that is generally amphipathic. The lipids typically comprise a hydrophilic component and a hydrophobic component. Exemplary lipids include, for example, fatty acids, neutral fats, phosphatides, oils, glycolipids, surface active agents (surfactants), aliphatic alcohols, waxes, terpenes and steroids. The phrase semi-synthetic (or modified natural) denotes a natural compound that has been chemically modified in some fashion ([0036]). With regards to "organic nanotubes" the disclosure at [0012] teaches organic nanotubes are being used and developed to treat bacterial, viral and other diseases. Certain activation agents such as pore forming agents are being developed to address drug resistance problems in bacteria and other microorganisms. In addition, limited toxicity studies in mice have shown that some of these self-assembling materials may be effective for in vivo application (Bong, D. T, et al., "Self-Assembling Organic Nanotubes, Angew. Chem. Int. Ed. 2001, 40, 988-1011). These activation agents, can be easily synthesized, are flexible in design and can quickly self-assemble. However, non-targeted activation agents have limited utility in therapeutic applications. First of all, the activation agents can not be delivered site specifically and remain questionable regarding overall efficacy, and ability to self-assemble in vivo. Secondly, the naked dosing of activation agents to patients is likely to cause severe immunological or toxicological problems. Lastly, targeting of these components can be a problem. A mere statement that all above mentioned generic compounds would be desirable for formation of liposomes for therapeutic delivery does

not sufficiently provide ample written description pages describing the full breadth of the liposomes with biological activity as instantly claimed. The specification does provide examples of what qualify as compounds of the claimed invention (see, e.g., EXAMPLES), however, these are limited to: Example 1 ([0100]-[0104]) refers to previous art in the area of activation agents, but does not present any data. Example 2 ([0102]-[0104]) refers to selection of activation agents potentially using in vitro testing, but does not present any data. Example 3 ([0105]-[0108]): refers to prior art in the area of encapsulation vehicles, however, data is also not presented. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of polymer with any biomolecule. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of liposomes made with a number of lipopeptides enclosing nanotubes as to represent adequately the genus instantly claimed. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222

USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11, 14-22, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghadiri (US 7,288,623) in view of Cullis et al. (US 6,417,326).

Ghadiri teaches inactivated organic nanotubes comprising a cyclic peptide, wherein the cyclic peptide comprises a cyclic D,L- α -peptide. Ghadiri teaches that the molecular tubes may be used as drug carriers, molecular sieves, reaction vessels and membrane channels. (e.g., abstract, last sentence and column 3, lines 15-25). The limitation of claim 2: --wherein the inactivated organic nanotube comprises a cyclic peptide—is taught, e.g., in column 2, lines 18-34. The limitation of claim 3: wherein the

cyclic peptide comprises a cyclic D,L- α -peptide-- is taught by the structures in Figures 9-16. The limitation of claim 4: --wherein the cyclic D,L α -peptide comprises 1 to 38 amino acids—is taught, e.g., in column 2, lines 35-54. The limitation of claim 5: --wherein the inactivated organic nanotube is activatable-- is taught, e.g., in Figure 17 and column 3, lines 1-14. The limitation of claim 11: --wherein the inactivated organic nanotube is from 1 to 38 aminoacids-- is taught, e.g., in column 2, lines 35-38. The limitation of claim 17: --wherein the cyclic peptide comprises one or more glutamic acid residues--, the limitation of claim 18: --wherein the cyclic peptide comprises one or more amino acids having at least one ionizable side chain—and the limitation of claim 19: --wherein the cyclic D,L α peptide comprises one or more ionizable amino acids that when exposed to a pH which allows protonation sufficient to cause self assembly of the cyclic D,L α peptide will cause the cyclic D,L α peptide to self assemble into a supramolecular structure-- are taught, e.g., in Figure 17 and column 3, lines 1-14. The limitation of claim 20: --wherein the pH is below about 7.0—is taught, e.g., in Figure 7. The limitation of claim 21: --wherein the cyclic D,L α peptide comprises an amino acid having at least one ionizable side chain, the amino acid selected from the group consisting of aspartic acid, glutamic acid, lysine, arginine, tyrosine, ornithine, histidine, serine and cysteine-- is taught, e.g., in Figures 9-12 and 16.

Ghadiri et al. do not expressly teach enclosing the nanotube in a liposome.

Cullis et al. teach a liposome for introducing a drug or therapeutic compound (e.g., column 1, lines 7-11, 25-41) into a cell into a cell, comprising: (a) a lipopeptide, said lipopeptide including a lipid covalently attached to a peptide; and (b) a therapeutic

compound enclosed in the liposome (e.g., column 3, lines 14-30). Cullis et al. teach that liposomes are vesicles comprised of one or more concentrically ordered lipid bilayers which *encapsulate an aqueous phase* (e.g., column 1, lines 25-27) and controlling the release of the therapeutic agents using fusogenic liposomes (e.g., column 2, lines 44-67; column 3, lines 1-30). The liposomes of Cullis et al. can accumulate at a target organ, tissue or cell and without the need for any external stimulus, become fusogenic, thereby releasing any encapsulated or associated therapeutic agent in the vicinity of the target cell, or fusing with the target cell plasma membrane introducing the therapeutic agent into the cytoplasm (e.g., column 2, lines 12-37), with the advantage that, by avoiding the endocytic pathway, the therapeutic agent would not be exposed to degradative enzymes that could inactivate the therapeutic agent (column 2, lines 37-42). Cullis et al. also teach the therapeutic compounds (such as proteins and peptides) may be carried in the aqueous interior of liposomes (e.g., column 3, lines 60-64). The limitation of claim 14: --wherein the lipid is attached to the peptide by way of an amide bond-- is taught, e.g., in claim 1, lines 1-5. The limitation of claim 15: -- wherein the lipopeptide comprises a fusion peptide— is taught, e.g., in claims 1-2. The limitation of claim 16: --wherein the lipopeptide comprises a lysine residue at the C-terminus is taught, e.g., in claim 2. The limitation of claim 22: --comprising a pharmaceutically acceptable carrier— is taught, e.g., column 29, lines 4—57. The limitation of claim 49: -- wherein the lipid is selected from the group consisting of a naturally occurring lipid, a synthetic lipid or a semisynthetic lipid-- is taught, e.g., in claim 3. The limitation of claim 50:-- wherein the lipid is a naturally occurring lipid-- is taught, e.g., in claim 1, Myr-

FEAALAEALAEALA, wherein the naturally occurring lipid is myristic acid (Myr). See also column 34, last paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Ghadiri by using a liposome as taught by Cullis et al. to administer it. The skilled artisan would have been motivated to do so because Ghadiri teaches that the nanotubes may be used as drug carriers, molecular sieves, reaction vessels and membrane channels. (e.g., abstract, last sentence and column 3, lines 15-25) which are desired near the cells, and because the liposomes of Cullis et al. can accumulate at a target organ, tissue or cell and without the need for any external stimulus, become fusogenic, thereby releasing any encapsulated or associated therapeutic agent in the vicinity of the target cell, or fusing with the target cell plasma membrane introducing the therapeutic agent into the cytoplasm (e.g., column 2, lines 12-37), with the advantage that, by avoiding the endocytic pathway, the therapeutic agent would not be exposed to degradative enzymes that could inactivate the therapeutic agent (column 2, lines 37-42). There would have been a reasonable expectation of success, given that the therapeutic compounds (such as nucleic acids, proteins and peptides) may be carried in the aqueous interior of liposomes as taught by Cullis et al. (e.g., column 3, lines 60-64). Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghadiri (US 7,288,623) in view of Cullis et al. (US 6,417,326).

Cullis et al. and Ghadiri are relied upon as above.

Ghadiri teaches that the cyclic peptide spontaneously assemble into molecular tubes at acidic pH but resist assembly into molecular tubes at alkaline pH (e.g., column 3, lines 5-10).

Cullis et al. teach that liposomes are vesicles comprised of one or more concentrically ordered lipid bilayers which *encapsulate an aqueous phase* (e.g., column 1, lines 25-27).

Ghadiri and Cullis et al. do not teach the aqueous phase having a pH from about 7.0 to about 14.5-- or the aqueous phase being maintained at a pH from about 7.0 to 14.5--.

Kelly teaches liposome to deliver therapeutic agents (e.g., abstract) and that the pH of the liposome may be adjusted by contacting the liposome system with a pharmaceutically acceptable mineral acid, organic acid or buffer solution (e.g., claims 20-21). Kelly also teaches, e.g., the aqueous pH being 8.0 (e.g., column 3, lines 8-11) and adjusting it to a lower pH (e.g., column 3, lines 11-16) to protect the therapeutic agent from alkaline degradation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Cullis et al. by adjusting the pH of the aqueous solution contained by the liposome to a specific pH from about 7.0 to 14.5 using acceptable acids or buffers to adjust the pH as taught by Kelly (e.g., column 3, lines 8-16 and claims 20-21). The adjustment of particular conventional working conditions (e.g., adjusting the pH in the aqueous solution contained within such

liposome) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., pH of aqueous solutions containing the therapeutic agents), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation (“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2145.05). One would have been motivated to determine all optimum and operable conditions in order to achieve appropriate conditions for the peptide nanotubes as taught by Ghadiri et al. (e.g., column 3, lines 5-10, which teaches that the cyclic peptide spontaneously assemble into molecular tubes at acidic pH but resist assembly into molecular tubes at alkaline pH) in the most efficient manner. One would have had a reasonable expectation for success because such modifications are routinely determined and optimized in the art through routine experimentation.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Marcela M Cordero Garcia
Patent Examiner
Art Unit 1654

MMCG 01/08

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654